

### **REMARKS**

Applicant recognizes with appreciation that Claim 20 will be allowable if rewritten in independent form and Claims 6, 7 and 9 will be allowable if rewritten to overcome rejections under 35 U.S.C. 112.

In this Amendment, Applicant has cancelled Claims 1 – 30, without prejudice or disclaimer, and added new Claims 31 – 42. Claims 31 – 42 have been added to overcome the rejection and further specify the embodiments of the present invention. It is respectfully submitted that no new matter has been introduced by the added claims. All claims are now present for examination and favorable reconsideration is respectfully requested in view of the preceding amendments and the following comments.

### **REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

Claims 3 – 7 and 26 – 30 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

It is respectfully submitted that in view of presently claimed invention, the rejection has been overcome. More specifically, Claims 3 – 7 and 26 – 30 have been cancelled without prejudice or disclaimer. Therefore the rejection is moot. The newly added Claims 31, 35 and 39 include clearly defined “a gas emitting battery” or “an electrolysis cell with a hydrogel or electrolyte” disposed in the housing. In addition, the method Claims 29 and 30 have been deleted and the newly added claims do not include method claims.

Therefore, the indefinite rejection is overcome. Accordingly, withdrawal of the rejections under 35 U.S.C. § 112 is respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 102:

Claims 1 – 3, 6, 8, 10, 11, 14 – 19 and 21 – 24 have been rejected under 35 U.S.C. § 102 (b) as allegedly being anticipated by Winsel (U.S. Patent 5,242,565), hereinafter Winsel. In addition, Claims 1, 3, 6, 8, 10 – 15, 17 – 19, 21 and 24 – 30 have been rejected under 35 U.S.C. § 102 (b) as allegedly being anticipated by Bunt WO 98/33452, hereinafter WO '52.

Applicant traverses the rejection and respectfully submits that the present-claimed invention is not anticipated by the cited reference. More specifically, Claims 3 – 7 and 26 – 30 have been cancelled without prejudice or disclaimer. Therefore the rejection is moot. The new Claims 31 – 42 include the imitations of a closure to the outlet, at least one deployable retention member, a battery powered electrical circuit including a switch capable of being actuated to commence the generation of a gas. Especially, Claims 31, 35 and 39 include subject matters deemed allowable by Examiner as contained in Claims 6, 7, 9 and 20, respectively. Claim 31 specifies that the electrical circuit provides a continuous rate of gas production and *in vivo* constant sustained release of the active agent. Claim 35 specifies that the electrical circuit with a microprocessor to control a discontinuous current provides a discontinuous rate of gas production and provides *in vivo* a constant sustained release of said active agent when the gas moves the piston. Moreover, Claim 39 has been amended to specify that the closure of the outlet is capable of being removed, ruptured or dissolved in body fluids and the action of gas generation will provide *in vivo* a constant sustained release of active agent. The dependent claims include the same limitations due to their dependency on claims 31, 35 and 39. The support for these newly added claims can be found throughout the specification.

Winsel discloses a galvanic cell having gas generating electrode. It is respectfully submitted that Winsel does not disclose the added features as indicated above. For example, Winsel does not teach a closure of the outlet which can be removed, ruptured or dissolved in body fluid, nor at least one deployable retention member. In addition,

Winsel does not disclose that the electric circuit providing a continuous or discontinuous current and action of gas generation providing *in vivo* a constant sustained release of the active agent. Moreover, Winsel does not disclose that the active agent is progesterone formulated in a liquid vehicle.

Similarly, although WO '52 discloses an intravaginal substance delivery device for achieving and maintaining certain progesterone level, it fails to teach or suggest the inventions as defined in the presently amended Claims 31 – 42. For example, WO '52 does not disclose a deployable retention member, the selected microprocessor to control the electrolysis cell or gas emitting cell, or a enclosure that is capable of being removed, ruptured under the pressurization of the liquid within said housing upon energisation of the battery electrical circuit.

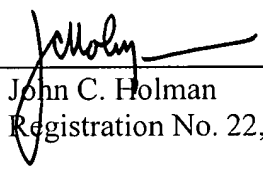
Therefore, the newly presented claims are not anticipated by Winsel or WO '52 and the rejection under 35 U.S.C. § 102 (b) has been overcome. Accordingly, withdrawal of the rejections under 35 U.S.C. § 102 (b) is respectfully requested.

Having overcome all outstanding grounds of rejection, the application is now in condition for allowance, and prompt action toward that end is respectfully solicited.

Respectfully submitted,

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